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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	61350C	8566

109 7590 12/19/2007

The Dow Chemical Company
Intellectual Property Section
P.O. Box 1967
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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,112	SIMON ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of the amendment filed on 10/19/2007. Upon entering the amendment, claims 1-13 are amended. Claims 1-123 are currently pending and presented for the examination.

Terminal Disclaimer

2. The terminal disclaimer filed on 10/19/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. 6,908,609 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

3. Applicant's arguments filed on 10/19/2007 with respect to claims under 35 U.S.C 112 first paragraph and 103(a) have been fully considered but they are not persuasive. However, upon amendment of claims, 112 first paragraph rejection is withdrawn and 103(a) rejection is maintained and made **FINAL**.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being obvious over Berger et al. (4,470,975) in view of Samejima et al. (EP 0077956) and Thompson et al. (US 5,004,603) together.

The claims are directed towards a method for increasing fluid loss through the feces in a host comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces, wherein the water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological saline. .

Berger discloses a composition and method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by administrating to said animal dextrans: a polysaccharide that is a polymer made of monomers of carbohydrate moieties in form of gel grains (see abstract, column 1, line 54-56. and column 10, lines 5-30). Berger also discloses a composition and method for

treating abnormal excess accumulation of fluid within the body, such as congestive heart failure, cirrhosis of the liver, nephrosis and other renal diseases associated with fluid retention in said animal (see column 1, lines 63+). Berger also discloses the insoluble cross-linked polysaccharide polymer may be ingested by the patient and during passage of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in the normal manner. Patients with renal failure cannot excrete all of the fluid and electrolytes needing excretion, total body levels of sodium, potassium, calcium, phosphate, chloride, water and various traces minerals ingested in their diet are usually higher than normal. Exclusive fluid retention and abnormal hormonal production causes hypertension. The conventional treatment for diseases of this nature is periodic hemodialysis. Consequently, patients on renal dialysis usually are receiving numerous medications to control their blood pressure, hormonal status, fat levels, and serum chemistries. Thus it has been found that certain insoluble hydrophilic, cross-linked polysaccharides are useful pharmaceutical agents for the treatment of abnormal excess accumulation of fluid within the body, such as, congestive heart failure, cirrhosis of the liver, nephrosis, and other renal diseases associated with fluid retention (see column 1 and 2).

Applicant's claims differ in that because they require a method for treatment of excess fluid by directly administering to the intestinal tract of the host and polymerizing a monomer comprising acrylic acid or salts thereof in removing fluid or edema when Berger is taken in View of Samejima with Thompson, because, Samejima with

Thompson together discloses a method for removing fluid or edema from the gastrointestinal tract of an animal by administering an enteric-coated microcapsule comprising water-swellable polymeric material in the core and the monomers of acrylic acid polymer is capable of absorbing at least 10 times its weight of fluid.

Samejima discloses an enteric-coated microcapsules comprising water-swellable polymer material in the core, said polymer is capable of absorbing water (1.2-1.5 times its weight, see page 5, lines 10-22, page 6, line 9 and page 27 lines 1-5). Patent '956 also discloses the composition in the form of enteric microcapsule is capable of releasing easily the active component in intestinal tract and maintains the active component (core material) effectively in the stomach (see page 2, lines 16-20). The patent '956 also discloses that the composition is in granule formulation (see page 22, line 1-10).

Thompson discloses a method of administering a composition to ruminants, such feeding composition comprising polymers derived from monomers such as (rneth)acrylic acid and (meth)acrylamide that is capable of absorbing water and swell by a factor (w/w) of at least 10-50 times its weight (see column 3, lines 35-60).

When these references are taken together, one would have been motivated to make a composition comprising of water-absorbent polymer and use the composition in the form of tablet or capsule for treatment of excess fluid in the intestinal tract to maximize therapeutic efficacy. By coating the composition with enteric polymer, one of ordinary skill would expect to obtain an intact and therefore effective composition for removing excess fluid from the body— without the enteric coating, the polymer in the

composition (e.g. polysaccharides) would be more susceptible to degradation by the acidic environment of the stomach (see Berger patent col 4, line 55-60 for the suggestion or motivation for enterically coating the composition). As suggested by cited reference, one would have reasonably expected successful removing of excess fluid in a body by directly administering an effective amount of a water-absorbent polymer to the intestinal - tract of the host because the effectiveness, extra benefits (i.e., absorbing at least 10-40 times its weight in physiological saline) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a)

Applicant's arguments filed on 10/19/2007 have been fully considered but they are not persuasive.

Applicant asserts that Berger fails to disclose directly administering to the intestinal tract of a host a water-absorbent polymer.

It is well known that gastrointestinal tract starts at mouth and ends at rectum. Given the instant claim set the broadest reasonable interpretation and further during the oral administration of medicament is means; it passes through intestinal tract of a host and would read the claimed subject matter of the instant application. And further, according to Berger invention, it was noted that the water content of feces of rats

treated with insoluble, hydrophilic, cross-linked dextrans is significantly higher than that of untreated rats (see col. 2, lines 29-36).

In response to applicant's argument that Samejima and Thompson does not cure the deficiencies of Berger, it is noted that Samajima and Thompson was relied upon for showing an effective amount of a water-absorbent polymer is capable of absorbing at least 10 times its weight in physiological silane environment. It is prima facie obvious to combine two compositions and methods each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846,850,205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the, shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Primary Examiner
Art Unit 1618